NATIONAL INSTITUTES OF HEALTH

WARREN GRANT MAGNUSON CLINICAL CENTER
CLINICAL CENTER QUALITY ASSURANCE COMMITTEE & CLINICAL PATHOLOGY DEPARTMENT
POINT OF CARE COMMITTEE

PROCEDURE: POINT OF CARE TESTING: PROCEDURE FOR TESTING SPECIFIC GRAVITY OF URINE BY REFRACTOMETER

Signature on File in Clinical Pathology Department

Formulated: 12/4/98
Implemented:
Revised:
Reviewed: Jan. 2000, No changes required

A. Use

The refractometer (TS meter) is used for rapid screening testing of **URINE** specimens for specific gravity. The test utilizes an estimate of the solute concentration of urine. This test will be used in various clinical situations including:

1) protocols requiring the procedure
2) post-operatively after neurosurgery

B. Essential Information

Specific gravity results are the ratios of the densities of a solution and the density of an equal volume of water. The TS meter uses principles related to light, speed and angle of light passing through specimens and air via a prism. A refractive index is created and is comparable to the direct measurement of specific gravity. Use the TS meter to test only urine for specific gravity. Do not use the TS meter to test specimens such as cerebral spinal fluid or blood.

C. Abbreviations

TS Meter	Total Solid Meter Refractometer	QA	Quality Assurance
CCS	Clinical Chemistry Service	QC	Quality Control
CAP	College of American Pathologists		

D. Limitations of the procedure

- Temperature:

1. The specimen of urine must be at room temperature or between 60 to 100 degrees F. For patients with fevers = 100 degrees F, obtain urine specimen and wait about 10 minutes for specimen to reach room temperature. Do not test specimens that are refrigerated.
2. Keep TS meter at room temperature between 60 – 100 degrees F.

- Linearity (Specific gravity results that can be tested with the TS meter)

  The reportable range for the TS meter is 1.000-1.035.

- Contrast Dyes

  Patients receiving contrast dyes can have falsely elevated specific gravity values. The duration of the effect of contrast dyes on specific gravity of urine is dependent on the type and amount of the dye as well as the kidney function of the patient. Check with the physician about the appropriateness of testing specific gravity in patients who have received contrast dyes.

- Alcohol Consumption

  Alcohol consumption can alter the values for specific gravity. Check with the physician about the appropriateness of testing specific gravity in patients who have ingested ethanol.

- Reference Ranges:

  (Clinical norms random urine) 1.002 — 1.035
  (Clinical norms 24 hr. urine) 1.015 — 1.024

- Clinical Considerations

  Notify MD for specific gravity results > 1.035 or results of 1.000. A specific gravity reading of 1.000 is consistent with distilled water. Specimens with specific gravity > 1.035 as found in renal failure, severe dehydration, or interferences of an undetermined nature, require different laboratory testing such as osmolality.

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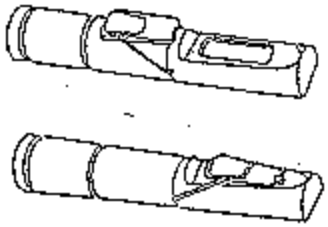
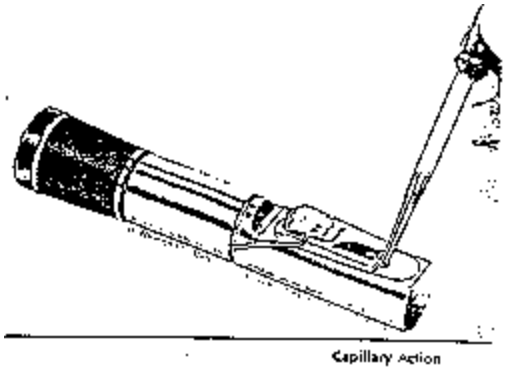
E Equipment

- Gloves
- Lens wipe tissues dampened with tepid water
- Dry lens wipe tissues

- T.S. Meter (Goldberg ® Refractometer Leica) model 10400A tested for precision and accuracy by Clinical Chemistry Service (CCS)
- (Disposable single use) Tuberculin syringe (without needle) or plastic pipette
- Control solutions both low and high (at room temperature) supplied by CCS (phone 6-3386)
- Clear urine specimen without additives at room temperature

Procedure

STEPS	KEY POINTS
1. Verify that the TS meter is clean and dry.	Use of a wet meter will cause inaccurate results Use only water to cleanse prism and cover since chemicals or immersion of meter under running water will damage the device. Use lens wipe tissues to dry the TS meter
2. Flip the cover of the meter so that it rests on the top of the prism.	
3. Obtain solution to be tested. QC Testing if first test of day a. When using control solutions verify that controls (both high and low) are not expired and are at room temperature.	
b. If using urine specimens, obtain several drops of clear urine (at room temperature) using either a disposable pipette or syringe without a needle. Use a new disposable pipette or syringe for each test & discard after use.	b. The urine used for testing should be clear, without cloudiness or turbidity or sediment. Urine that is cloudy, turbid, or filled with sediment should be allowed to settle for 5-10 minutes. Draw the sample for testing once there is a clear layer of fluid in the specimen. Cloudy specimens are difficult to read.
4. Place urine specimen or QC material	"Diagram of TS meter "



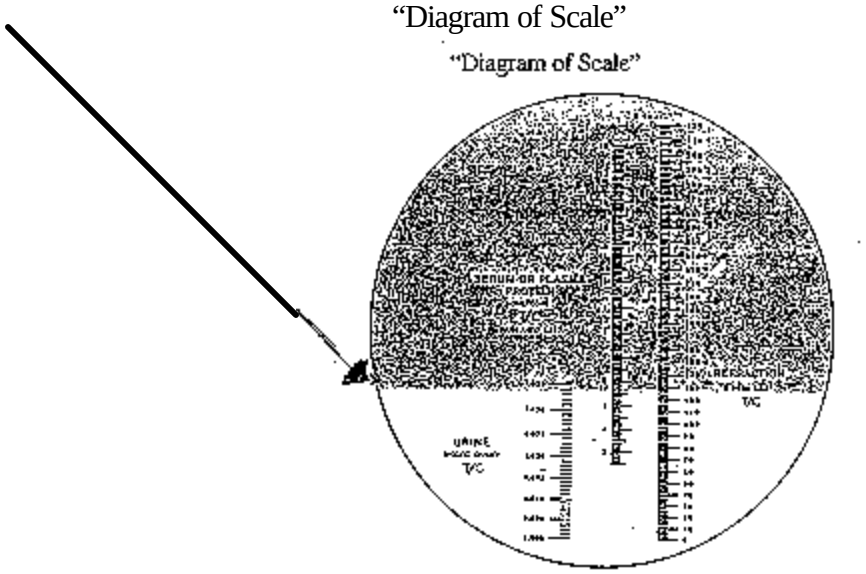
in groove of cover filling the chamber fully.

STEPS	KEY POINTS

5. Hold the meter horizontally to the light while pressing a gloved finger on the cover plate.

6. Rotate the eye piece until the scale comes into focus.
7. Read the scale at the mark where the light and dark Fields meet.

"Diagram of Scale"



8. Note the number appearing where the bright and dark fields cross the scale.

9. Document QC readings on the TS Refractometer Monthly QC form.

For QC testing both the high and low controls must fall within the range set by CCS. If QC is not within range or if TS meter malfunctions contact CCS and follow directions outlined in the appendix on troubleshooting the refractometer

10. Document specific gravity result, date, time, serial number of meter, specimen type (ex. urine specimen from catheter tube), purpose of testing, patient clinical signs and symptoms, and interventions in NIH approved record . Note: See Clinical Considerations section under "D. Limitations Of The Procedure"

NIH approved records include:
MIS (under tests guide)
Critical Care Flowsheet
Progress Notes (for outpatients)

11. Lift the plate cover, clean and dry the meter using lens wipes.

Use only water to cleanse the prism & cover of the TS meter.

F. Appendices

Requirements For Quality Control (QC) and Quality Assurance (QA) for Bedside Specific Gravity by Refractometry Using the TS Meter
Refractometer Monthly QC Form
Guidelines for Point of Care Testing
Troubleshooting the Refractometer

G. References

1. College of American Pathologists, Commission on Laboratory Accreditation Inspection Checklist, Urinalysis, Section: 3 A, Illinois, 1996

2. National Institutes of Health, Bethesda, MD Clinical Pathology Department, Quality Control (QC) and Quality Assurance (QA) Policy for Bedside Specific Gravity by Refractometry, 1998

3. National Institutes of Health, Bethesda, MD, Point of Care Committee Policy, Medical Administration Minutes, 1998

4. Brunzel, Nancy A, Fundamentals of Urine and Body Fluid Analysis, WB Saunders Co, Philadelphia, 1995, pp. 130-131, 484.

5. Reichert-Jung, Instructions for use and care of the Reichert-Jung TS Meter, Buffalo, NY, 1986

APPENDIX

Requirements For Quality Control (QC) and Quality Assurance (QA) for bedside Specific Gravity by Refractometry Using the TS Meter

I. General Information

A. The Leica Total Solids Refractometer is to be used **ONLY** for urine analysis.

B. All Quality Control materials should be formulated specifically for use on the Leica Total Solids Refractometer.

C. The QC material should contain a sufficient amount of analyze to monitor the assay effectively. Two levels, (high and low) of the QC material will be analyzed prior to the first patient of the day for every 24 hour period.

D. Quality Control materials will be obtained from the Clinical Chemistry Service (CCS) phone: (496-3386), building 10, 2C403. The QC material is **NOT** to be used beyond the expiration date. Old control solution should be discarded. CCS will check new lots of QC material before routine use by analyzing the new lot against the current lot. (The new lot will be run in parallel three times in duplicate for one day).

E. The Nursing units and Physicians will be notified by the QC Specialist when the QC ranges are changed.

II. Controls for Specific Gravity by Refractometry

The Leica Total/Solids Meter (T.S.) uses deionized water (1.000) and the Biovation Specific Gravity Control (1.020). The high and low control solutions should give results within the expected range when used according to the stated procedure, "Testing Specific Gravity of Urine by Refractometer".

III. QC Procedures

A. Responsibilities of the Operators

The Operator will document on the Refractometer Monthly QC Sheet.

1. Before the first patient tested in a 24 hour period, the operator must verify that both high and low QC materials were analyzed on the TS meter and that these tests gave acceptable results. If the testing was not done, or the results were not acceptable, the operator will not perform the test on the patient specimen. The patient specimen will be sent to Clinical Pathology for specific gravity testing. Continuing authorization of an operator to perform the Specific Gravity will depend an a satisfactory QC record.

2. Operators will perform CAP Proficiency testing (a skills check) using urine samples provided by the CSS three times a year in the Clinical Pathology lab area.

3. Remedial training will occur for both nurses and physicians. The remedial training will occur on the patient care unit, be documented and retained for two years by the Head Nurse and

Physicians. The Head Nurse is responsible for the evaluation of the nursing operator's competency in practice on an ongoing basis.

B. Review of QC Results/Head Nurse Responsibilities

A new refractometer Monthly QC Sheet will be started the first day of each month.

1. All QC results must be reviewed by the Head Nurse, Physician, or designee every week.

2. This review must be documented on each weekly QC report by signature, date, and any pertinent comments.

3. The Head Nurse will fax the completed QC record, with comments, for the current month to the QC Specialist in the CCS , (301) 02-1885, by the third of each month. This includes negative (i.e., no samples run for that month) reports.

4. If the QC Specialist does not receive the QC record by the close of business on the 3rd of the month, the Head Nurse will be notified. The CCS QC Specialist will review and sign the faxes, and retain them in the Clinical Chemistry Service for two years. The CSS QC Specialist will review the data for shifts and/or trends.

IV. Proficiency Tests

The Proficiency Testing will be performed by the authorized operators three times a year with all the refractometers that are in use for patient testing and with the reference refractometer of the CCS. Proficiency samples will be received by the CCS Specialist who will coordinate the testing schedule. The record will have the name and number of the operator, the nursing unit, the serial number and the NIH number of the refractometer, QC material lot number, QC results, and the Proficiency Test result.
When the evaluation is complete, a report will be reviewed and signed by the Chief of the Clinical Pathology Department. Any unacceptable results will be investigated by the CCS QC Specialist and CCS. All documentation will be maintained for two years by CCS.

V. Sample Comparison

The patient comparison will be performed three times a year at the times of CAP testing. The comparison will be made with the urine samples prepared by the Clinical Chemistry Service. The comparison samples will consist of one low, one normal, and one high urine sample. These urine samples will also be analyzed by the Clinical Chemistry Service with the reference Refractometer.

VI. Verification of Additional Instruments

A. New Leica Refractometers

All new refractometers must be verified in the Clinical Chemistry Service before they are placed into routine use. This will include evaluation of the precision and sample comparison with CSS reference Refractometer.. The new Refractometer will be accepted if the difference between the results between the result of the reference Refractometer and the new Refractometer is within the specified range determined by the Clinical Chemistry Service.

B. Malfunctioning TS Meter Leica Refractometers

If any signs of malfunctioning occur, the Refractometer must be returned to the Clinical Chemistry Service care of QC Specialist 2C 407. Prior to sending the meter to Clinical Chemistry Service, fax the QC data to the CCS QC Specialist. See the appendix on Troubleshooting the Refractometer.

Certification

a) Laboratory

Clinical Chemistry Service
Clinical Pathology Department
National Institutes of Health
Bethesda, Md. 20892

b) Date

December 4, 1998

c) **Signature**

Nadja N. Rehak, Ph. D.

Kathryn Lothschuetz Montgomery, RN, Ph. D.
Associate Director for Nursing

History of Method

The Urine Specific Gravity procedure was put into service in December 1998.

Review and Revision

Review Date	Senior Staff Signature	Revisions	Comments
12/15/1999	Nadja N. Rehak	no	no

APPENDIX

Refractometer Monthly QC Form

Please FAX to CCS QC Specialist at (301)402-1885 by the Third of the next Month

REFRACTOMETER MONTHLY QC FORM

PCU ____________ Manufacturer's serial # ______________________ NIH #: ____________

Month ____________ Control Lot # ____________ Expiration date ____________

Year ____________

Date	Low Control 1.000-1.003	Hi Control 1.019-1.023	Operator	Comments	Reviewer

Weekly review: ______________ Date: ________

Date	Lo Control 1.000-1.003	Hi Control 1.019-1.023	Operator	Comments	Reviewer

Weekly review: ______________ Date: ________

Date	Low Control 1.000-1.003	Hi Control 1.019-1.023	Operator	Comments	Reviewer

Weekly review: ______________ Date: ________

Date	Low Control 1.000-1.003	Hi Control 1.019-1.023	Operator	Comments	Reviewer

Weekly review: ______________ Date: ________

Date	Low Control 1.000-1.003	Hi Control 1.019-1.023	Operator	Comments	Reviewer

Weekly review: ______________ Date: ________

11/30/98

Monthly Summary Comments:

Reviewer: ______________

Date: ______________

APPENDIX: GUIDELINES FOR POINT OF CARE TESTING

Each designated unit will comply with the following established criteria:

- Head nurse and Physicians will request specific point of care testing with rationale.
- Associate Director of Nursing will approve unit request and forward to Clinical Center Point of Care Committee
- Each point of care test will have a clearly defined Quality Control Program monitored by the Head Nurse for nursing staff and by Physicians when they perform the test and reviewed quarterly by the Clinical Pathology Department.
- Point of care testing will not be used for the purpose of clinical decision making
- Results of point of care testing must be validated by laboratory tests prior to clinical decisions.
- Quality Control Documentation forms will be maintained at the unit level for a period of 2 years.
- The Head Nurse of the approved units will review the QC data weekly
- Staff will be approved for point of care testing after successful completion of an educational program and proficiency testing as designated by Clinical Chemistry Services.

APPENDIX: Troubleshooting the Refractometer